REMARKS

Claims 27-74, 81-119, and 122 were previously pending in this application, and stand variously rejected in the most recent Office Action dated February 5, 2009. Upon entry of this amendment, all previous claims are cancelled, and new claims 123-184 are added.

Interview Summary

On December 16 and December 17, 2008, applicant's representative spoke with Examiner Schlientz by telephone about the Restriction between these two groups:

- Group I: concentrated hormone compositions, along with methods of using such concentrates to prepare pharmaceutical products for hormone replacement;
- Group II: methods for producing concentrated hormone compositions.

On December 17, applicant's representative elected Group I for prosecution on the merits.

Applicant hereby confirms election of Group I. This election is made *without traverse*.

Allocation of New Claims

Claims 123-138 recite concentrated hormone compositions, and accordingly fall within Group I of the Restriction. Claims 140-158 recite a plurality of such concentrated hormone compositions (as part of a system for compounding pharmaceutical products), and accordingly fall within Group I. Claims 160-178 recite a method for using such compositions for preparing medicine for hormone replacement, and accordingly also fall within Group I.

Claims 139 and 159 recite methods for producing concentrated hormone compositions, and accordingly fall within Group II of the Restriction. Thus, these claims are currently withdrawn from examination.

Claims 179-180 recite a method for hormone replacement therapy. Claims 181-184 recite control methods for assessing medicines compounded for hormone replacement. Applicant believes these claims can be examined with the claims in Group I without imposing an undue burden on the Examiner, since they depend from and incorporate limitations from the claims already present in Group I. However, in the event that the Office wishes to divide these claims from Group I, applicant does not traverse the withdrawal of these claims from the group under examination.

In summary, claims 123-138, 140-158, and 116-178 are under examination. Claims 139 and 159 withdrawn from examination. Claims 179-184 are subject to assessment for inclusion in the group under examination.

In the event the Office determines that a further Restriction of the claimed invention is required, he is invited to contact the undersigned by telephone, who is prepared to make a further election by phone following consultation with the applicant.

Support for claim amendments

Entry of the claim amendments does not introduce new matter into the disclosure. The amendments are supported throughout the specification and claims as originally presented. Paragraph references below refer to the application as published (US 2004/0180866 A1).

- Penetration enhancing solvents comprising only ethoxy diglycol and propylene glycol (claims 123-125): ¶¶ [0125], [0160]
- Composition is essentially free of water (claim 123): inherent in the 50% ethoxy diglycol:50% propylene glycol mixture. Furthermore, water is explicitly recited in ¶ [0125], and so may be explicitly excluded: MPEP § 2173.05(i).
- Estrogen at 40 mg/mL (claim 126): ¶ [0244]
- Androgen at 150 mg/mL (claim 128): ¶ [0162]
- Progestagen at 200 mg/mL (claim 130): ¶ [0099]
- Estradiol, estrone, estriol, testosterone, DHEA, pregnenolone, and progesterone (claims 127, 129, 131): claim 2 as originally presented
- Single concentrated reagent comprising a plurality of estrogens (claim 132): ¶¶ [0092] and [0093]
- Solvent or wetting agent for dissolving or suspending the hormone (claim 132): ¶ [0122], claim 4 as originally presented
- Estrogen at 10 to 60 mg per gram (claim 133): ¶¶ [0092] and [0093]
- Particular combinations of estriol, estradiol, and estrone (claims 135-137): claims 6 and 8 as originally presented
- Use of an ointment mill or homogenizer to prepare concentrated steroid hormone solutions (claims 139 and 159): ¶ [0316]

- A system for compounding pharmaceutical products, comprising a plurality of concentrated hormone reagent compositions (claims 141 ff.) and the method of using such compositions for compounding (claims 160 ff.): ¶¶ [0295] to [0303] and throughout the disclosure
- Graduated dispensing device (claim 142): ¶ [0296]
- Using the invention for custom tailoring or individualizing the pharmaceutical product according to the needs of each consumer (claims 141 ff. and claims 160 ff.): ¶¶ [0007], [0013], [0079], and [0190]
- Doctor prescribed concentration of each bio-identical hormone (claim 161): ¶ [0297]
- Combining a plurality of concentrated solutions (claims 152, 153, 162): ¶ [0295]
- Separate pharmaceutical carrier (claims 155 and 163): ¶¶ [0297], [0304], and [0305]
- Color coding each reagent composition as a means of quality control (claims 156-157, 177-178, and 181-184): ¶¶ [0181] to [0186], [0305] and [0318].
- Method of hormone replacement therapy (claims 179 and 180): ¶ [0297] and throughout the disclosure.

These amendments are made to obtain coverage for certain aspects of the invention that are of current commercial interest. Applicants reserve the right to introduce claims to additional subject matter previously claimed or described in the specification in this or any related application.

Objections and rejections under 35 U.S.C. § 112

In the Office Action dated February 5, 2009, the specification and certain claims were objected to; certain claims were rejected under § 112 ¶ 1 for reciting new matter; and certain claims were rejected under § 112 ¶ 2 for being indefinite.

All these concerns have been addressed by way of the revisions to the specifications and the claims made in this Amendment. Withdrawal of these rejections is respectfully requested

Prior art rejections

Certain claims stand rejected under 35 U.S.C. § 102 as lacking novelty over U.S. Patent 2,,856,329 (Taylor), WO 90/11064 (Chiang), WO 97/24148 (Chen), WO 02/11768 (Carrara), U.S. Patent 6,248,363 (Patel), US 2003/007297 A1 (Chen), U.S. Patent 4,076,811 (Lachnit-Fixson), and/or U.S. Patent 3,828,106 (Rudel). Other claims stand rejected under § 103 as being obvious over a combination of the Lachnit-Fixon patent with U.S. Patent 6,708,822 (Muni), or a combination of the published applications by Chiang and Chen ('297).

Applicant respectfully submits that none of these rejections applies to the claimed invention as currently presented.

The patent disclosure focuses in large part on a new technology that allows the retail pharmacist to compound each hormone replacement product separately, and tailor each one to the needs of each consumer, in accordance with their doctor's recommendations.

As explained in the specification, previous methods of generating hormone replacement products involved combining powdered hormone preparations with the solvent and carrier system used for dispensing. This meant that compounding and any customization had to be done by large manufacturing facilities having all the necessary equipment and safety measures in place.

The system described in the specification provides an important advance over prior art manufacturing methods, because it places the final compounding and customization in the hands of the retail pharmacist in the form of the concentrated hormone compositions. As a result of this system, the pharmacist can prepare a product for each consumer by combining the prepared hormone compositions in appropriate amounts, adjusting the concentrations appropriately, and then adding a prepared carrier mixture to finish formulation of the product as an ointment, cream, gel, or paste — and do all these things without having to have access to the special equipment that is normally used and being subject to the safety concerns of prior art methods. The system may also have a color coding system that allows the pharmacist to do a simple but important quality control check to ensure that each customized product is adequately mixed and contains the desired ingredients.

The pharmaceutical compounding system of this invention benefits not only the pharmacist, but also the consumers in the wide-spread market for hormone replacement therapy, who have considerably improved access to customized medicine as a result of this invention by Dr. Mamchur.

The claims now presented in this application are designed to capture aspects of this new pharmaceutical compounding system.

Claims 123-131 are explicitly limited to concentrated hormone compositions using a solvent system comprising both *ethoxy diglycol* and *propylene glycol,* with the additional proviso that the solution is *anhydrous.*

As described at ¶ [0160] of the application, the inventor discovered only after extensive research that the combination of ethoxy diglycol and propylene glycol has a special ability to dissolve estrogens and testosterone, including combinations of estriol, estradiol, and estrone substantially better than any of the other in a long list of solvents tested. The superiority of this particular solvent combination is not taught or suggested in any of the references alone or considered together, and could not be predicted from anything in the cited references without the benefit of hindsight from what is taught in this application.

As emphasized throughout the specification, the ability to produce high concentration and properly solubilized liquid hormone compositions is important in enabling the pharmacist to make products having a full range of possible concentrations to suit the needs of each consumer.

Claims 132-138 are expressly limited to *concentrated liquid compositions* comprising a *combination* of different estrogens.

No such combination is taught in the cited references. The estrogen combinations in the examples of the Lachnet-Fixson patent are powdered compositions. The estrogen combinations referred to in the Muni patent are combinations present in the final product at more dilute concentrations suitable for therapy. In contrast, the compositions covered by these claims contain amounts of two or more estrogens at concentrations that are unsuitable for human therapy without further processing. The pharmacist uses this as a reagent in preparing a customized hormone replacement medicine, by mixing with other reagents such as reagents containing other hormones, reagents that act as diluents, and/or reagents that provide a medium for producing a final product that is an ointment, cream, gel or paste. Without the teachings contained in this application, there would be no motivation for someone reading any of the cited references to make such a concentrated solution of an estrogen combination.

Claims 140-158 and 160-184 explicitly cover the combination of concentrated reagents that make up the compounding system of this invention, and its use to make hormone replacement products custom tailored to the needs of each consumer.

This important aspect of the invention was not captured by the claims as previously presented. None of the cited prior art references place final compounding and customization of hormone replacement therapy into the hands of the retail pharmacist, as described in this application and recited in these claims. Accordingly, these claims are both novel and non-obvious.

Claims 156-157, 177-178, and 181-184 further incorporate the color coding system of this invention for use in quality control. Prior art refers to coloring that may be added into the final product (presumably for purposes of identification, esthetics or marketing). In contrast, this application directs the manufacturer of the compounding system of the invention to place the colorants into the concentrated reagent solutions. This has an actual function in the compounding of the medication, enabling the pharmacist to get a direct readout of the ingredients and mixing of the final product. The cited references do not teach or suggest a system of coding using different colors for quality assurance purposes.

For all of these reasons, the claims in this application are patentable over the prior art of record. Withdrawal of all rejections under §§ 102 and 103 is respectfully requested.

Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

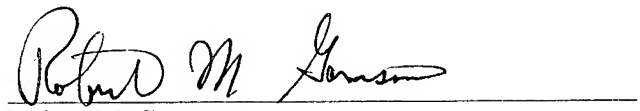
In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

Fees due

Ninety six claims, 7 independent claims, and multiple dependent claims were previously paid for in this application. Upon entry of this amendment, there are 62 claims and 4 independent claims. Accordingly, no fees are believed payable with respect to entry and consideration of this Response.

Nevertheless, should the Patent Office determine that a fee is due in connection with the filing of this paper, applicants hereby authorize such charges to be billed to Deposit Account No. 50-3875.

Respectfully submitted,



Date

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